REMARKS

Claims 1 and 8-31 have been withdrawn. The Applicant has added new claims 32-38. Claims 2-7 and 32-38 are under consideration.

Claim 2 has been amended to incorporate certain elements from non-elected claims. Claim 2 has also been amended to recite, "wherein the polypeptide has at least one activity characteristic of B7RP1" and to recite "high stringency conditions." Support for amended claim 2 can be found in original claim 2 and throughout the specification, for example at page 41, line 32, through page 42, line 6; and page 23, lines 24-29.

Claim 3 has been amended to incorporate certain elements from non-elected claims. Claim 3 has also been amended to recite, "wherein the polypeptide has at least one activity characteristic of CRP1" and to recite "high stringency conditions." Support for amended claim 3 can be found in original claim 3 and throughout the specification, for example at page 41, line 32, through page 42, line 6; and page 23, lines 24-29.

Claims 4-7 have been amended to correct claim dependencies.

Support for claim 32 can be found throughout the specification, for example in original claim 2, and at page 23, line 24-29, and Figures 2 and 3. Support for claim 33 can be found throughout the specification, for example in original claim 2, and at page 41, line 32, through page 42, line 6, and Figures 2 and 3. Support for claim 34 can be found throughout the specification, for example page 46, lines 9-19; page 41, line 32 through page 42, line 6, and Figures 2 and 3. Support for claim 35 can be found throughout the specification, for example, at page 23, lines 24-29, and Figure 12. Support for claim 36 can be found throughout the specification, for example, at page 23, lines 24-29; page 41, line 32 through page 42, line 6; and Figure 12. Support for claim

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37 can be found throughout the specification, for example, at page 23, lines 24-29; page 41, line 32 through page 42, line 6, and Figure 12. Support for claim 38 can be found throughout the specification, for example, at page 23, lines 24-29, and Figure 12.

Thus, the claims are fully supported by the application as originally filed and the amendment adds no new matter.

Drawings

The Examiner requested correction to the Brief Description of the Drawings. See Action at page 2. The Applicant has amended the Brief Descriptions of the Drawings to reflect the numbering used in the Figures and to describe each individual panel, as requested. The description of Figure 13 was also amended to correct the misidentification of terms listed in the parentheses. The description of Figure 1B was amended to restore a sentence that was inadvertently replaced by ellipsis in a previous amendment. The amendments add no new matter.

Title

The Examiner requested that the title be amended. See Action at page 3. The title has been amended to remove the word "novel" as requested. The Applicant respectfully reminds the Examiner of the obligation to examine subject matter not elected in a generic claim, if the elected subject matter is patentable. Pending claim 3 is a generic claim that includes certain CRP-1 polynucleotides. Accordingly, the Applicant asks that the Examiner hold the request to amend the title in abeyance until allowable subject matter is determined.

Abstract

The Examiner objected to the Abstract. See Action at page 3. A replacement Abstract is enclosed.

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Specification

The Examiner objected to subject matter contained in an Amendment filed October 28, 2002. See Action at page 3. Paragraph and line numbers in that Amendment contained errors. In addition, the Amendment inadvertently contained changes to a non-existent paragraph. Thus, the Examiner objected to the introduction of new matter. The Applicant has cancelled the Amendment and have replaced it with the present Amendment, which accurately reflects the pagination of the specification and which contains no new matter.

Claim Objections

The Examiner objected to claim 3 as being dependant from non-elected claims. See Action at page 4. Claim 3 has been amended to incorporate certain elements from non-elected claims. Claim 3, as amended, does not depend from a non-elected claim.

The Examiner objected to claim 2 for reciting inaccurate SEQ ID NOs. See Action at page 4. Those SEQ ID NOs have been corrected.

Rejections Under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 2-7 under 35 U.S.C. § 112, second paragraph, for allegedly "failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention." Action at page 4.

A) The Examiner rejected claims 2-7 under 35 U.S.C. § 112, second paragraph, noting that claim 2 recites polypeptides as set forth in certain SEQ ID NOs, but that the recited SEQ ID NOs are "for a nucleic acid sequence, not the polypeptide sequence." Action at page 4. The SEQ ID NOs in that claim have been corrected.

B) The Examiner rejected claims 2-7 under 35 U.S.C. § 112, second paragraph, alleging that the "recitation of 'hybridizes under stringent conditions' in claim 2(h) is

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ambiguous." Action at page 4. Solely to expedite prosecution and without acquiescing to the Examiner's rejection, the Applicant has amended claims 2 and 3 to recite, "under high stringency conditions." None of the rejected claims, as amended, recites "hybridizes under stringent conditions." Thus, the rejection is moot.

C) The Examiner rejected claims 5-7 35 U.S.C. § 112, second paragraph, noting that those claims "each recite 'the host cell of claim 3,'" and further noting that claim 3 does not recite a host cell. Action at page 4. Those claims have been corrected to recite the "host cell of claim 4."

The Applicant requests reconsideration and withdrawal of all rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, first paragraph (written description)

The Examiner rejected claims 2-7, under 35 U.S.C. § 112, first paragraph as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention." Action at page 5. The Applicant respectfully traverses this rejection. The Examiner discussed certain terms used in the claims which will be addressed in turn.

A) "Percent Identity Variants"

The examiner rejected certain claims that "recite a genus of nucleotide sequence encoding polypeptides having at least about 70% identity to a reference sequence, but do not require that the encoded polypeptides share any testable functional activity, a feature deemed essential to the instant invention." Action at page 4. The Applicant respectfully traverses this rejection and disagree that functional activity is "essential to the instant invention." Certain of the original claims did not recite activity. Furthermore,

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the specification recites certain uses for nucleic acid molecules that encode polypeptides that are not biologically active. For example, the specification recites:

> CRP1 or B7RP1 nucleic acid molecules, fragments, and/or derivatives that do not themselves encode polypeptides that are biologically active may nonetheless be useful as hybridization probes in diagnostic assays to test, either qualitatively or quantitatively, for the presence of CRP1 or B7RP1 DNA or corresponding RNA in mammalian tissue or bodily fluid samples.

Specification at page 27, lines 7-14. Solely to expedite prosecution and without acquiescing to the Examiner's contentions, claim 2, section (c) has been amended to recite "a nucleotide sequence encoding a polypeptide that is at least about 70 percent identical to the polypeptide as set forth . . . wherein the polypeptide has at least one activity characteristic of B7RP1." Solely to expedite prosecution and without acquiescing to the Examiner's contention, claim 3, section (c) has been amended to recite "a nucleotide sequence encoding a polypeptide that is at least about 70 percent identical to the polypeptide as set forth . . . wherein the polypeptide has at least one activity characteristic of CRP1." Accordingly, all of the claims that recite a percent identity also recite an activity. Thus, the Examiner's rejection is moot.

The Examiner stated that, "[i]n the absence of a particular testable function and some structural basis for that function that must be maintained by members of the genus, the claimed invention is not described in such a way as to reasonably convey to on of ordinary skill in the art that the inventor, at the time the application was filed, had possession of the invention." Action at page 5. Nucleotides that encode polypeptides which are at least 70% identical to a polypeptide having a particular sequence identification number recited in the claims are specifically structurally related to such

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sequences. Thus, adequate structure is provided, and the claimed invention is adequately described.

B) "Fragments"

The Examiner rejected certain claims alleging that "[f]ragment language that encompasses open (comprising) claim language permits unidentified flanking sequence to be added to the recited subsequence of a particular SEQ ID NO and so does not allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." Action at page 6. The Applicant respectfully traverses this rejection.

To support this rejection, the Examiner cited *Vas-Cath Inc. v. Mahurkar,* 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In that case, the Federal Circuit held that the lower court "erred in applying a standard that essentially required the drawings [relied upon by the applicant] to *necessarily exclude* all diameters other than those within the claimed range." *Id.* at 119 (emphasis original). Rather, the Court said, the "proper test is whether the drawings conveyed with reasonable clarity to those of ordinary skill that [the applicant] had invented the catheter recited in the claims." *Id.* Similarly, the test here is not whether the specification describes every possible flanking sequence. Rather, the test is whether the specification conveys the claimed invention with "reasonable clarity to those of ordinary skill." *Id.* The specification adequately conveys the claimed invention to one of ordinary skill.

Furthermore, the transitional phrase "comprising," which "leaves the claim open for the inclusion of unspecified ingredients even in major amounts," is permitted. See The Manual of Patent Examining Procedure, Eighth Edition, August 2001 (MPEP) § 2111.03. Accordingly, claims that recite the transitional phrase "comprising" always

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encompass material that is not described in the specification. The Examiner has provided no support for a conclusion that the term "comprising" renders a claim unpatentable under the written description requirement of § 112, first paragraph. Therefore, the fact that claims 8, 10, 12, and 19-23 encompass "unidentified flanking sequence" because they recite the transitional phrase "comprising" is not a proper basis for rejection.

C) "Allelic Variants and Splice Variants"

The Examiner rejected certain claims that recited "allelic variants" and "splice variants." See Action at page 6. Solely to expedite prosecution, the Applicant has amended the claims so that none of the present claims specifically recite the terms "allelic variant" or "splice variant." Thus, the Examiner's rejection is moot. Consequently, the Applicant does not address the contentions made by the Examiner. However, the Applicant does not acquiesce to the Examiner's rejection and reserves the right to add claims specifically reciting allelic variants and/or splice variants.

D) "Hybridizes Under Stringent Conditions"

The Examiner rejected certain claims for reciting "hybridizing under stringent conditions." See action at page 6. Specifically, the Examiner rejected such claims for failing to "require that the hybridizing nucleic acids hybridize under any particular conditions," and because "there is no requirement that the hybridizing nucleic acids encode polypeptides that share any particular function" with the disclosed polypeptides. Id. Solely to expedite prosecution and without acquiescing to the Examiner's contentions, claims 2 and 3 have been amended to recite "hybridizes over its entire length under high stringency conditions." Claim 2 has also been amended to recite "wherein the polypeptide has at least one activity characteristic of B7RP1." Claim 3 has

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also been amended to recite "wherein the polypeptide has at least one activity characteristic of CRP1." Thus, the rejection is moot.

Rejections Under 35 U.S.C. § 112, first paragraph (enablement)

The Examiner rejected claims 2-7 alleging that those claims were not reasonably enabled by the specification. See Action at page 7. The Applicant respectfully traverses this rejection. The Applicant will again address the Examiner's remarks regarding certain terms.

A) "Encoding Variant Polypeptides"

The Examiner alleged that "the experimentation left to those skilled in the art to determine which 'variant' sequences would still result in polypeptides having the same function as the human and mouse B7-RP1 polypeptides disclosed in the specification as filed is unnecessarily, and improperly, extensive and undue." Action at page 7. The Applicant respectfully traverses this rejection.

First, it is noted that none of the rejected claims recite the term "variant."[1] Claims 2, and 3 do recite nucleotides that encode polypeptides "that are at least about 70% identical" to disclosed polypeptides. Solely to expedite prosecution and without acquiescing to the Examiner's arguments, claim 2 has been amended to recite "wherein the polypeptide has at least one activity characteristic of B7RP1." Solely to expedite prosecution and without acquiescing to the Examiner's arguments, claim 3 has been amended to recite "wherein the polypeptide has at least one activity characteristic of CRP1." Guidance for such claims is provided. See, e.g., page 43, line 31, through page 46, line 19.

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[1] Claims 2 and 3 did recite the terms "allelic variants" and "splice variants," however the Examiner addressed those terms separately from "variants." See Action at page 8C.

The Applicant asserts that it is not necessary that one skilled in the art be able to predict precisely which changes in a polypeptide will not affect activity, because modifying a polypeptide and testing it for activity does not involve undue experimentation. First, the Applicant asserts that it was within the skill in the art at the time the application was filed to use standard molecular biology techniques to make fragments of a polypeptide comprising the amino acid sequence of particular sequence identification numbers or encoded by nucleotide sequences of particular sequence identification numbers. Second, the Applicant asserts that it was within the skill in the art at the time the application was filed to make polypeptides that are at least about 70% identical to those polypeptides or fragments. Finally, the Applicant asserts that it was within the skill in the art at the time the application was filed to determine if such polypeptides or polypeptide fragments have at least one activity characteristic of B7RP1 or CRP1.

The Applicant asserts that to make those polypeptides or polypeptide fragments and determine their activity does not constitute undue experimentation. Rather, that process is analogous to the process of making and screening monoclonal antibodies, which the Federal Circuit found not to be undue experimentation in *In re Wands*, 858 F.3d 731, 8 U.S.P.Q.2d 1400 (Fed. Cir.1988). In that case, the court held that the test for undue experimentation "is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine...." *Id.* at 737.

The Applicant therefore asserts that making and screening polypeptides and polypeptide fragments also does not involve undue experimentation.

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B) "Fragments Comprising"

The Examiner rejected claims that "recite in various forms polypeptides comprising 'fragments' of certain number of amino acids residues of the various SEQ ID NOS." Action at page 7. The Examiner alleged that "before the skilled artisan can make polypeptides comprising 'fragments' with additional flanking sequence, guidance is required with respect to the identity of those flanking sequences." The Applicant respectfully traverses this rejection.

The Examiner again focused on the transitional phrase "comprising," stating that that phrase "opens the claim up to the inclusion of additional residues of undisclosed identity and number flanking the recited 'fragment.'" Action at page 7. As discussed previously, that transitional phrase, which always leaves the claim open to additional unknown material, is permitted. Accordingly, the fact that a claim encompasses additional unknown flanking sequences is not a proper basis for a rejection.

Furthermore, the specification does provides guidance for polypeptides comprising fragments. For example, the specification describes the construction of a B7-RP1-Fc fusion protein in which B7-RP1 polypeptide was fused to the Fc region of IgG1. See Specification at page 31, lines 7-30 and Example 7. One skilled in the art will readily appreciate that such a fusion protein could be made with a fragment of a B7-PR1 polypeptide. Additionally, such a fusion protein could be made using a protein other than the Fc region of IgG1.

C) "Allelic Variants" and "Splice Variants"

The Examiner rejected claims reciting the terms "allelic variants" and "splice variants" as allegedly not enabled. Action at page 7. Solely to expedite prosecution, the Applicant has amended the claims such that none of the present claims specifically

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recite "allelic variant" or "splice variant." Thus, the Examiner's rejection is moot. Consequently, the Applicant does not address the contentions made by the Examiner. However, the Applicant does not acquiesce to the Examiner's rejection and reserves the right to add claims specifically reciting allelic variants and/or splice variants.

D) "Hybridization"

The examiner rejected certain claims alleging that, "hybridization language in the absence of a testable function and limitations regarding both the hybridization conditions and the sequence length over which the hybridization takes place; does not allow the skilled artisan to make and use the hybridizing nucleic acids commensurate in scope with the instant claims without undue experimentation." Action at page 9.

Solely to expedite prosecution and without acquiescing to the Examiner's contentions, claims 2 and 3 have been amended to recite, "hybridizes over its entire length under high stringency conditions" Claim 2 has been amended to recite "wherein the nucleotide encodes a polypeptide that has at east one activity characteristic of B7RP1." Claim 3 has been amended to recite "wherein the nucleotide encodes a polypeptide that has at east one activity characteristic of CRP1." Thus, the rejection is moot.

The Applicant respectfully requests reconsideration and withdrawal of the § 112, first paragraph rejection based on the written description requirement.

Rejections Under 35 U.S.C. § 102

Ishikawa

The Examiner rejected claims 2-4 and 7 as allegedly "being anticipated by Ishikawa et al (DNA Res. June 1998; 5:169-176, see entire document) as evidenced by GenBank Accession No. AB014553 (released 06 Feb 1999)." Action at page 10.

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First, as the Examiner pointed out, SEQ ID Nos: 6, 7, 11, and 12 were disclosed in parent application USSN 09/244,448, filed February 3, 1999, as were SEQ ID NOs. 1 and 2. Thus, the priority date for those sequences is February 3, 1999, three days before the release of GenBank Accession No. AB014553 on February 6, 1999. Therefore, that GenBank data is not prior art against claims to sequence ID Nos: 1, 2, 6, 7, 11, or 12. Solely to expedite prosecution and without acquiescing to any of the Examiner's contentions, the Applicant has amended claims 2-7. Those amended claims do not recite SEQ ID NOs: 16 or 17.

Second, Ishikawa cannot anticipate the current claims. For a reference to anticipate it must disclose every element of the claim. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986). Moreover, the reference must be enabling. *See* MPEP § 2121.01. "A reference contains 'enabling disclosure' if the public was in possession of the claimed invention before the date of invention." Id.

Ishikawa broadly discusses 100 proteins isolated from human brain cDNA libraries. It provides a few characteristics of those 100 proteins, such as length of cDNA and apparent molecular weight. See Table 1. Ishikawa also categorizes the 100 proteins "based on homologies to known proteins." As the Examiner pointed out, Ishikawa notes that KIAA0653 is 32.9% identical to "CD80-like protein precursor." See Table 2. That scant information is not sufficient to enable one of skill in the art to isolate or identify a polynucleotide of claims 2-4 or 7. Accordingly, Ishikawa did not "put the public in possession of the claimed invention" at the time of the filing of the application. Therefore, Ishikawa is not an enabling disclosure and cannot anticipate the present claims. It is noted that although later-disclosed data can be used to establish inherency,

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an anticipating reference must be fully enabling at the time the application is filed. See MPEP §§ 2121, 2131, and 2124.

GenBank Accession No. R23544

The Examiner rejected claims 2, 4, and 6 under 35 U.S.C. § 102(b) as allegedly being anticipated by GenBank Accession No. R23544. See Action at page 11. To support that rejection, the Examiner pointed to certain regions of identity of that sequence with certain regions of SEQ ID NOs: 11 and 16. For a reference to anticipate it must disclose every element of the claim. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986). The sequence of GenBank Accession No. R23544 does not disclose every element of any of claims 2, 4, or 6.

Solely to expedite prosecution and without acquiescing to any of the Examiner's contentions, certain sub-parts of claim 2 have been amended. GenBank Accession No. R23544 does not anticipate claim 2, as amended, because it fails to teach every element of any of the sub-parts of that claim. For example, GenBank Accession No. R23544 encodes a polypeptide that is less than at least about 70 percent identical to the sequence of SEQ ID NO: 7 or SEQ ID NO: 12. Further, GenBank Accession No. R23544 does not discuss activity for a polypeptide encoded by the sequence. For at least those reasons, GenBank Accession No. R23544 does not anticipate claim 2. Claim 4 recites the nucleic acid of claim 2 and claim 6 depends from claim 4. Since the polypeptide of claim 2 is not anticipated by GenBank Accession No. R23544 for at least the reasons discussed, claims 4 and 6 are likewise not anticipated.

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Genbank Accession No AA510455

The Examiner rejected claims 2, 4, and 6 under 35 U.S.C. § 102(b) as allegedly being anticipated by Genbank Accession No AA510455. See Action at page 11. To support that rejection, the Examiner pointed to certain regions of identity and homology of that sequence with certain regions of SEQ ID NO: 6. For a reference to anticipate it must disclose every element of the claim. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986). The sequence of GenBank Accession No AA510455 does not disclose every element of any of claims 2, 4, or 6.

Solely to expedite prosecution and without acquiescing to any of the Examiner's contentions, certain sub-parts of claim 2 have been amended. GenBank Accession No AA510455 does not anticipate claim 2, as amended, because it fails to teach every element of any of the sub-parts of that claim. For example, GenBank Accession No AA510455 encodes a polypeptide that is less than at least about 70 percent identical to the sequence of SEQ ID NO: 7 or SEQ ID NO: 12. Further, GenBank Accession No. AA510455 does not discuss activity for a polypeptide encoded by the sequence. For at least those reasons, GenBank Accession No AA510455 does not anticipate claim 2. Claim 4 recites the nucleic acid of claim 2 and claim 6 depends from claim 4. Since the polypeptide of claim 2 is not anticipated by GenBank Accession No AA510455 for at least the reasons discussed, claims 4 and 6 are likewise not anticipated.

Rejections Under 35 U.S.C. § 103

The Examiner rejected claims 5 and 6 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ishikawa in view of Linsley. See Action at page 12. Those claims recite a host cell comprising a nucleic acid molecule of claim 3, which the

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Examiner rejected as allegedly being anticipated by Ishikawa. The Examiner cited Linsley as allegedly showing certain additional elements of claims 5 and 6.

For at least the reasons stated above, Ishikawa does not anticipate claim 3. Moreover, Linsley does not remedy the deficiencies of Ishikawa. Because the polypeptide of claim 3 is patentable over Ishikawa in view of Linsley, claims 5 an 6 are likewise patentable. Moreover, the Applicant need not address the Examiner's contentions with respect to other elements of those claims. By not addressing those contentions, the Applicant in no way acquiesces to those contentions.

Double Patenting

The Examiner provisionally rejected claims 2-7 under 35 U.S.C. § 101 as "claiming the same invention as that of claims 2-7 of copending Application No. USSN 09/728,420." The Examiner noted that this is a provisional double patenting rejection since the allegedly conflicting claims have not been allowed. The Applicant requests that this provisional rejection be held in abeyance until allowable subject matter is determined.

Conclusion

The Applicant respectfully asserts that the application is in condition for allowance. If the Examiner does not consider the application to be in condition for allowance, the Applicant requests that the Examiner call the undersigned ((650) 849-6601) to arrange an interview prior to taking action.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: May 5, 2003

By: _____
Clifford E. Ford
Reg. No. 52,903

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By: Nancy Foster

E
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Abstract

Polypeptides comprising ligands and receptors involved in T-cell activation are disclosed. Nucleic acid molecules that encode such polypeptides, and vectors and host cells for expressing polypeptides are also disclosed. In certain embodiments, the polypeptides, agonists thereof, and antagonists thereof may be used to treat T-cell mediated disorders.

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